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1300 I Street NW
Washington DC 20005-3315

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,746,680

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,746,680, which claims the human drug product MERIDIA® (sibutramine hydrochloride monohydrate), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be five years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of five years.

The period of extension has been calculated using the Food and Drug Administration (FDA) determination of the length of the regulatory review period published in the Federal Register of December 28, 1998 (63 Fed. Reg. 71493). Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (3,486 - 852) + 837
= 2,154 days (6 years)

Since the regulatory review period began January 23, 1986, before the patent issued May 24, 1988, only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From May 24, 1988 to January 23, 1986 is 852 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 4,746,680

Granted: May 24, 1988

Original Expiration Date[1]:	June 11, 2002
Applicant:	James E. Jeffery et al.
Owner of Record:	Knoll Aktiengesellschaft
Title:	Therapeutic Agents
Classification:	514/646
Product Trade Name:	MERIDIA® (sibutramine hydrochloride monohydrate)
Term Extended:	Five Years
Expiration Date:	June 11, 2007

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 872-9411
Attn: Karin Tyson

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: MERIDIA®
FDA Docket No.: 98E-0755

[1]Subject to the provisions of 35 U.S.C. § 41(b).